New Point Oyster Co.
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April 20,1999

William K. Hubbard, Assoc. Commissioner
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Request for Comment: Performance Standard for Vibrio vulnificus

The Center for Science in the Public Interest (CSPI) has petitioned the Food and Drug Administration (FDA) to establish a performance standard of "nondetectable" for the marine bacterium Vibrio vulnificus in raw molluscan shellfish harvested from waters that have been linked to illness from this organism. The FDA has requested comment on this and several specific questions.

In the first instance, CSPI seeks to separate "Gulf Coast" oysters from those of the Atlantic and Pacific coasts, it cannot. Federal regulation needs to meet "equal protection" standards, otherwise it is subject to myriad complaints and challenges. Moreover, Vibrio vulnificus exists in all oysters and no reliable science exists that can pinpoint with any reliable precision, where, how or why a particular oyster has a high count and another does not, much less, what would constitute an infective dose or for whom? Nor can anyone predict how or when a change in environment or pathology could occur which would change these results in a particular place. Where a government regulation poses the possibility of devastating an industry and denying over 200 million Americans their choice of a healthy protein source, more precision and justification is imperative.

One might believe that the above claims are exaggerations, however it is only logical that if a "nondetectable" standard " from waters that have been linked to illnesses from this organism" is adopted then the following sequence is likely to result: technology and testing improvements will prove that Vibrio vulnificus is detectable in all oysters; other pathogens and problems (i.e. Vibrio parahaemolyticus, fecal coliforms and heavy metals)will also surface or " be exposed for the public good" to justify expanded regulation; the "linked waters" criteria will quickly disappear and; the legal standard for what is reasonable and prudent in the industry will be shifted to "processed" thus eliminating the sale of "live molluscan shellfish". This will eliminate 80% of the growers and more importantly, 80% of raw bar consumers. There is NO similarity in product!

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There is no substituting a live animal with it's own organism controlling metabolic processes and retaining fluids (liquor) for one that has been killed. All processes contemplated kill the animal and envision a rubberband holding it shut. This opens a Pandora's Box of possibilities of real danger to the consuming public with the probability of occurrence greatly exceeding that associated with V. vulnificus. It is a long established custom to never eat an animal that is open, dried out or discolored. These are automatic visual warnings to consumers and handlers that something is wrong. All of this will be eliminated and incidents of food poisoning will increase dramatically. The only saving grace will be that dramatically fewer people will be eating the product as demand will be greatly diminished. It is possible that processing at point of sale or service would escape detection and reduce product deterioration but there are serious handling risks and shortcomings associated otherwise.

For this commentator there is a much greater consideration that is being entirely overlooked in the present setting. If regulations of this nature are adopted, they will have negative environmental consequences for the Chesapeake Bay. For the last five years a significant effort has been made by volunteers, industry and government to restore oysters in the Bay and rebuild the commercial oyster industry. The oyster, wiped out by disease and environmental degradation, plays a significant role as Nature's filter and has been identified by scientists as the linchpin of the environmental health of the Chesapeake. The effort has begun paying off as populations are just beginning to show signs of reemergence. This is due in large part to the three thousand "home gardeners" and twenty small commercial growers who have tended the animals that turned the tide. A regulation of this nature and the negative publicity would drive out a number of these "home oyster gardeners" because they would no longer feel safe eating from their gardens and virtually all of the small oyster farmers such as New Point would be forced out due to costs. If all economic incentives are eliminated the restoration effort will likely fail and the industry will cease to exist. This has vast economic, cultural, historic and environmental consequences to the region.

New Point Oyster Company was formed to assist in rebuilding consumer trust and demand for the Chesapeake Bay oyster and to provide a marketing vehicle for small growers. It grows and markets oysters that are grown in floats on top of the water. Some scientists believe that avoiding contact with the mud on the bottom greatly reduces the incidence of V. vulnificus. This has yet to be determined or proved. New Point operates with a wet storage permit issued by the Virginia Department of Shellfish Regulation under HAACP training and regulations. There would seem to be ample mechanism under the present system to provide the appropriate regulatory structure to suitably protect the public. . We strongly urge the FDA to reject this petition and to support the regimen presently in effect. We also urge the FDA to continue and strengthen it's above mentioned research efforts with added emphasis on #3 determining infectious dose levels for both V. vulnificus and V. parahaemolyticus. There is a very good likelihood that if a nondetectable standard were set and any processing requirement imposed New Point would cease operations. The oyster industry is now infantile in the Chesapeake and any disincentive would have a multiplier effect and dramatically impact the resource.

Comment on Questions

1. This technology does not really fit with production operations in the majority of instances. Producers are too small to handle it and the time delays would exacerbate risks and operations. The shipping and handling costs are greatly increased and not reflected in the $.08 per unit cost estimate. In fact, total associated costs would be increased a minimum 100%. It has been previously stated that equipment may be an option at point of service or sale where economies of scale can be derived and freshness issues avoided.

2. There are two other processes that may be similar but fail for the same reasons as previously mentioned in general comment and number 1 above.

3. Unknown. They are not practical and should be imposed anywhere. If marketers can justify this by their particular circumstance they should do so due to their own individual considerations.

4. This standard is unusually strict and cannot be justified under any circumstances. Has there even been an accurate measure of what parts per gram translates into? Is this parts per Trillion or even to the next power beyond that? 100 parts per gram is still a small dose and definitive research should be conducted .

5. It should not be set for any but if it is justified by good science that should be controlling.

6. This has been addressed previously. The processing salesman has grossly understated the costs of this process. The handling, shipping, packaging, and losses are understated if included at all. There are also significant opportunity and societal costs which are not addressed. Additionally, the increased sickness and liability issues that are substituted because of likely problems with spoilage are not factored in.

7. Unrealistic standards and false confidence benefit none. The company that is pushing this would enjoy increased sales and short term profits but would ultimately suffer from diminished markets.

8. There is no possible justification for any standards to be set. The number of incidents of sickness are relatively small. The CSPI claims in it's materials that "over 9000 people die and tens of millions become ill each year" . It would seem that the same efforts and resources would be better utilized in an area that has a higher incident rate. It would be more beneficial to accurately determine the dose level range that infection or sickness would be reasonably predictable. Obviously science is limited in its abilities and the universe of variables much too great to go beyond that.

New Point Oyster Co.

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